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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,377	05/22/2000	James J. Hickman	215177-00101	2330

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EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/575,377	HICKMAN, JAMES J.	
	Examiner	Art Unit	
	Marianne P. Allen	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-50 have been cancelled. Claims 51-73 have been newly added and are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments filed 11/26/04 have been fully considered but they are not persuasive.

Claim Objections

Claims 52 and 55 are objected to because of the following informalities: Claim 52 contains a typographical error "ore" and claim 55 appears to contain a typographical error "if" instead of –of--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 51-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 51-73 have been newly added and no basis has been pointed to in the specification for the claimed methods and none is apparent. In particular, limitations such as "an intervening layer...that provides a high impedance seal...and allows a deconvolution step to be performed..." are not seen. Applicant is requested to point to basis for all claims.

Claims 51-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claim 51 is directed to a method for identifying one or more ion channels of a cell; however, the only step in the method is "exposing a test substance to a device and accompanying software." The claims are not enabled as merely exposing a test substance to a device will not identify one or more ion channels of a cell. Critical method steps are missing from the claims.

Claims 51-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51 is directed to a method for identifying one or more ion channels of a cell; however, the only step in the method is "exposing a test substance to a device and accompanying software." The remainder of the claim describes the device but does not add any more steps to achieve the goal of the preamble. As such, the claim is confusing as merely exposing a test substance to a device will not identify one or more ion channels of a cell.

Claim 57 is confusing in failing to clearly indicate where the insulator is positioned with respect to the microelectrode surface, intervening layer, and/or cells. As the intervening layer must be in contact with the microelectrode surface and this same layer must provide a high

impedance seal with a cell, it appears that the insulator must be above or on top of the cell. It is unclear what "outside the electrode" means. Clarification is requested.

Claim 61 is confusing for depending upon cancelled claim 10.

Claim 67 does not appear to further limit claim 66 in that all nucleic acid sequences encompassed by claim 66 would have known or unknown function. As such, claim 67 does not appear to differ in scope. Clarification is requested.

Claim 70 is confusing for depending upon cancelled claim 1.

Claim 73 is confusing in reciting "deconvolution ... provides information on pathways in the cell." It is not clear what deconvolution analysis provides the recited information. The claim as written does not make clear what specific information must be provided to meet the limitation of the claims.

Claim Rejections - 35 USC §103

With respect to the claims, the declaration provided by inventor Hickman on 11/26/04 asserts that "high impedance" is synonymous with "high resistance" in the context of this invention. That is, a seal such as in patch clamping meets the limitation of the claims.

Claims 51-67 and 70-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borkholder et al. (US 6,377,057 B1) in view of Georger et al. (U.S. Patent No. 5,324,591).

Borkholder et al. discloses a method for identifying one or more ion channels of a cell that may be affected by a test substance by deconvoluting a change in cell membrance potential by exposing a test substance to a device and using software to analyze changes in action potentials. Disclosed is a system having a high throughput capacity comprising a device and accompanying software. The device and accompanying software is a biosensor for use in

evaluating the effect of test compounds on ion channels in excitable cells. The test compounds contemplated include genetically active drugs and peptides. The microelectrode records from single cells in contact with it. The microelectrode has platinum black electroplated on it. Insulators such as silicon nitride can be used. Borkholder et al. contemplates using cells which are genetically altered by exogenous and endogenous gene manipulation. The cells can be stem cells, cardiac, or neuronal cells. Computer software and systems for action potential analysis (including temporal analysis) are disclosed. Experimental conditions can be altered. Data can be compared to reference data. Comparisons can be made using any suitable algorithm (i.e. power spectral analysis using fast Fourier transforms is not required). Frequency and shape characteristics can be evaluated. Ion flow or flux is reflected in the changed shape of the action potential. The microelectrode can be planar. Other biosensors can be used. (See at least abstract; claims; figures; columns 7- 8; column 10; column 11, line 5, through column 12, line 40; column 14, lines 14-35; column 16 lines 55-67.) Borkholder et al. does not specifically disclose an intervening layer positioned between the microelectrode and cells.

Georger et al. does teach such an intervening layer. Georger et al. teaches a cell-based biosensor comprising a substrate in contact with a culture medium. The cells are electrically excitable and are capable of producing a signal in response to a bioeffecting substance. The signal produced is detected and the used to assay the effect of drugs on the cells. Georger et al. teaches that the biosensor is comparable to a "loose patch" method of measuring electrical responses from neurons positioned over substrate-mounted microelectrodes. (That is, a high impedance or high resistance seal is formed between the electrode and the cell membrane.) (See at least columns 10-11.) The biosensor can be defined by a pattern of a self-assembled

monolayer. (See paragraph bridging columns 6-7.) Cell adhesion promoters and inhibitors can be used. (See at least columns 8 and 14.) The transducer can be a field effect transistor. Surface modifying agents such as silane can be used. Polymers (high viscosity mixtures) can be used. RGD containing peptides can be used. (See at least column 15.)

It would have been obvious to use the biosensor of Georger et al. in the system of Borkholder et al. as a mere matter of substitution. Borkholder et al. indicates that other biosensors can be used and Georger et al. teaches the advantages of the self-assembled monolayer and cell adhesion promoters and inhibitors on the substrate. Borkholder et al. further suggests using cells which are genetically altered by exogenous and endogenous gene manipulation.

With respect to claim 59, the specification and prior art of record make clear that hippocampal cells would have been well known to those of ordinary skill in the art as a neuronal cell type used in electrical recordings. Therefore, it would have been obvious to one of ordinary skill in the art to use this particular cell type.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Marianne P. Allen

Marianne P. Allen
Primary Examiner
Art Unit 1631

2/22/05

mpa